

**Readopt with amendment He-P 4040.01 through He-P 4040.03, effective 6/22/11 (Document # 9945-A), cited and to read as follows:**

**PART He-P 4040 REGISTRATION OF RADIATION MACHINES, MAGNETIC RESONANCE IMAGING MACHINES AND PROVIDERS OF SERVICES**

He-P 4040.01 Purpose. This part provides for:

- (a) The evaluation of the need for shielding for new and modified ionizing radiation facilities;
- (b) The process for the registration of ionizing radiation machines;
- (c) The process for the registration of magnetic resonance imaging (MRI) machines;
- (d) The process for the registration of persons providing radiation machine or MRI servicing, or services; and
- (e) The process for the approval of an out-of-state radiation or MRI machine to be brought into the State of New Hampshire.

He-P 4040.02 Scope. This part shall apply to each person:

- (a) In possession of an ionizing radiation or MRI machine;
- (b) Who wishes to dispose of or make a change of ownership of a radiation or MRI machine;
- (c) Who offers radiation or MRI machine servicing or services; or
- (d) Who wishes to bring a radiation or MRI machine, from another state, into the State of New Hampshire; and

He-P 4040.03 Shielding Plan Review.

(a) Prior to new construction or modification of existing installations utilizing ionizing radiation machines, a review of floor plans, shielding specifications, and equipment arrangements shall be completed as set forth in paragraphs (b)-(d) below to ensure that, once operational, no individual will receive a dose in excess of the limits prescribed in He-P 4020.

(b) All prospective and existing registrants shall utilize the design services of a registered service provider as described in He-P 4040.07.

(c) Each prospective or existing registrant may request the department of health and human services/radiological health section (DHHS/RHS) to provide an evaluation of an existing shielding plan review or to offer technical advice on shielding requirements for a radiation machine installation.

(d) The following information shall be submitted to DHHS/RHS with any request for a shielding plan review:

- (1) Distances where applicable, such as:
  - a. From the source of radiation to the patient;

- b. From the source of radiation to each point for which the shielding requirement is to be calculated; and
  - c. From the patient to each point for which the shielding requirement is to be calculated;
- (2) The normal location(s) of the system's radiation port;
  - (3) The travel and traverse limits of the radiation beam port(s);
  - (4) Direction(s) in which the useful beam will be directed;
  - (5) Locations of any windows, doors or other openings;
  - (6) The location of the operator's booth;
  - (7) The location of the control panel;
  - (8) The structural composition and thickness or lead equivalent of all existing or planned walls, doors, partitions, floor, and ceiling of the room(s) to be evaluated;
  - (9) The dimensions of the room(s) to be evaluated;
  - (10) The type of occupancy of all adjacent areas, including the space above and below the rooms(s), and, if there is an exterior wall, the distance to the closest area(s) where it is likely that an individual might be present;
  - (11) The make and model of the equipment, the maximum technique factors as defined in He-P 4041, and the output waveform;
  - (12) The type of examination(s) or treatment(s) to be performed with the equipment; and
  - (13) Information on the anticipated workload of the system(s) in milliamperere seconds (mAs) per week, milliamperere seconds being the product of the x-ray tube current and the exposure time.
- (e) After installation of a radiation machine, the registrant shall keep the following records for review during an inspection by DHHS/RHS until the registration is terminated:
- (1) The maximum rated technique factors, as defined in He-P 4041, of each machine;
  - (2) A scaled drawing of the room in which each stationary radiation machine system is located indicating the location of tubeheads, describing the use of each area adjacent to the room, and specifying an estimation of the extent of occupancy by an individual in such areas;
  - (3) The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; and
  - (4) The shielding plan review which shall include the type and thickness of materials, or lead equivalency, of each protective barrier.

(f) After installation of an MRI machine and until the registration is terminated, the registrant shall keep the following records for review during an inspection by DHHS/RHS:

- (1) A scaled drawing of the MRI suite indicating the location of reception, patient, prescreening, control room, MRI Machine, fire extinguishers and equipment;
- (2) An MRI suite safety protocol which shall be reviewed:
  - a. Annually; and
  - b. After any change is made to the MRI suite; and
- (3) Documentation that the local fire department is aware of the presence of MRI suite hazards in the event of an emergency response.

**Readopt with amendment He-P 4040.04, effective 6-22-11 (Document # 9945-A and Document # 9945-B), to read as follows:**

He-P 4040.04 Registration of Radiation or MRI Machines.

(a) Each person having possession of any ionizing radiation or MRI machine, except those specifically exempted in He-P 4040.06, or those applying for reciprocal recognition of an out-of-state radiation or MRI machine in accordance with 4040.11, shall register such machine with DHHS/RHS within 30 days after its acquisition.

(b) Each person leasing or renting a radiation or MRI machine as defined in He-P 4041 shall be subject to the machine registration requirements of He-P 4040.04.

(c) Application for registration of a radiation or MRI machine shall be made on FORM DHHS/RHS A “Application for Radiation or Magnetic Resonance Imaging Machine Registration” (May, 2015) provided by DHHS/RHS.

(d) The registration period shall begin on August 1 and end on July 31<sup>st</sup> of the following year.

(e) All registrations shall be renewable as described in He-P 4040.09.

(f) No person having possession of a radiation or MRI machine shall operate such machine or cause it to be operated until it is registered with DHHS/RHS pursuant to He-P 4040.04.

(g) DHHS/RHS shall issue a certificate of registration provided that the requirements of He-P 4040.04 and the applicable fee payment required under He-P 4070.06 have been met.

(h) The registrant shall retain the certificate of registration until it expires as per He-P 4040.08.

(i) The registrant shall notify DHHS/RHS in writing within 15 days of any change in the information submitted in the application for registration and contained on the certificate of registration.

(j) The disposal or change of ownership of any registered machine shall be made in accordance with He-P 4040.05.

(k) Each registrant shall be responsible for radiation protection in operations with each radiation machine.

(l) Each registrant shall prohibit any person from furnishing radiation or MRI machine servicing or services as described in He-P 4040.07 to a radiation or MRI machine or facility until such person provides a current certificate of registration as evidence that they are registered with DHHS/RHS as a provider of services.

(m) No person shall assemble, install or use radiation or MRI machines unless such machines, when properly placed in operation, meet the requirements of this chapter.

(n) Machines purchased during the month of July shall be registered according to He-P 4040.04(a), and shall be assessed the applicable fee set forth in He-P 4070 during the month of August.

(o) In addition to the requirements set forth in He-P 4040:

(1) All radiation and MRI machine registrants shall follow the requirements set forth in He-P 4001 through He-P 4003, He-P 4019 through He-P 4022, He-P 4041 and He-P 4045;

(2) Registrants utilizing analytical x-ray and radiation generating devices shall be subject to the requirements of He-P 4043;

(3) Registrants utilizing particle accelerators shall be subject to the requirements of He-P 4044;

(4) Registrants utilizing radiation or MRI machines for all diagnostic purposes, including veterinarians shall be subject to the requirements of He-P 4045 and He-P 4046;

(5) Registrants utilizing therapeutic radiation machines shall be subject to the requirements of He-P 4047; and

(6) Registrants engaged in industrial radiographic operations shall be subject to the requirements of He-P 4034.

**Adopt He-P 4040.05 to read as follows:**

He-P 4040.05 Disposal of or Change of Ownership of a Radiation or MRI Machine.

(a) A machine registration shall be non-transferable.

(b) A registrant shall submit a completed FORM DHHS/RHS D “Certificate - Disposition or Change of Ownership of Radiation or MRI Machine” (May, 2015) provided by DHHS/RHS when modifying the possession of a registered machine as follows:

(1) Upon disposal of a registered machine either by donation or disposal;

(2) Upon change of ownership of a business entity with a registered machine(s);

(3) Upon replacement of a registered machine by a registered service provider;

(4) Upon disposal of an originally registered machine unable to be repaired or calibrated; or

- (5) Upon the sale of a registered machine.

**Readopt with amendment He-P 4040.05, effective 6-22-11 (Document # 9945-A), and renumber as He-P 4040.06, to read as follows:**

He-P 4040.06 Exemptions.

(a) Any electronic equipment that produces ionizing radiation incidental to its operation shall be exempt from the requirements of this part provided that the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 5  $\mu$ Sv (0.5 millirem) per hour at 5 centimeters from any accessible surface of such equipment.

(b) Any radiation or MRI machine while in transit or in storage incident thereto shall be exempt from the registration requirements of this part.

(c) Domestic television receivers and video display terminals shall be exempt from the requirements of this part.

(d) Permanently inoperable radiation or MRI machines shall be exempt from the requirements of this part.

(e) Loaner machines, as defined in He-P 4041, shall be exempt from the requirements of this part as long as the loan does not exceed the 30 days. If the loaner machine remains in the state after 30 days, the registrant shall comply with He-P 4040.04, He-P 4040.05, and He-P 4070. The registrant shall submit written notification to DHHS/RHS regardless of the duration of use of the loaner machine. Notification shall include registrant name, and the machine make, model, serial number and acquisition date.

(f) Financial institutions that take possession of a radiation or MRI machine as a result of foreclosure, bankruptcy, or other default of payment shall be exempt from the requirements in this part to the extent that they demonstrate that the unit is only operable for the sole purpose of selling or leasing the unit.

(g) An individual employed by a registrant to perform, on an in-house basis only, calibrations, equipment performance evaluations, or minor repairs of that registrant's diagnostic or industrial radiation or MRI machines, shall be exempt from the service provider registration requirements of this part, unless the individual also provides these services to other registrants.

(h) The following shall not be exempt:

- (1) Electron beam welders;
- (2) Electron microscopes;
- (3) Providers of radiation or MRI machines for mobile services; and
- (4) Providers of service for electronic equipment in (a) above during testing or servicing.

**Readopt with amendment He-P 4040.07, effective 6-22-11 (Document #9945-A and Document #9945-B), to read as follows:**

He-P 4040.07 Application for Registration of Servicing and Services.

(a) Each person who is engaged in the business of installing radiation or MRI machines, or is engaged in the business of furnishing or offering to furnish radiation or MRI machine servicing or services as described in He-P 4040.07(b) shall apply for registration with DHHS/RHS prior to furnishing or offering to furnish such services.

(b) Application for registration of persons providing servicing or services shall be made on FORM DHHS/RHS SP “Application for Registration as a Provider of Radiation or MRI Machine-Related Services” (May, 2015) provided by DHHS/RHS.

(c) The applicant shall specify each applicable type of service being offered, choosing from the following:

(1) Therapy unit services as follows:

- a. Radiation therapy physicist as required by He-P 4047.04(k); or
- b. Calibration and compliance surveys of radiation therapy units;

(2) Installation and servicing of radiation or MRI machines, therapeutic radiation machines or radiation machines for other use and associated radiation or MRI machine components;

(3) Radiation protection consultation or surveys;

(4) Design of shielding or access controls for diagnostic, therapeutic or other facilities;

(5) Calibration of radiation or MRI machines, measurement instruments, or radiation devices;

(6) Personnel dosimetry services; or

(7) Distribution or sales of radiation or MRI machines.

(d) Each person applying for registration under He-P 4040.07 shall also provide the following:

(1) A description of the minimum education, training, and experience that the applicant will require of each individual who will provide services under this registration, as follows:

a. For installers, relative to radiation safety and any applicable federal or state regulations pertaining to the manufacture, assembly, installation, acceptance and quality control testing, and functioning of radiation or MRI machines; and

b. For radiation protection consultants and designers of shielding and access controls, relative to radiation safety and protection, including radiation surveys and measurement, instrumentation, shielding, and radiation protection engineering; and

c. For qualified experts, the individual shall:

- 1. Be certified in the appropriate field by the American Board of Radiology, the American Board of Health Physics, the American Board of Medical Physics or the American Board of Nuclear Medicine Science; or

2. Hold a master's or doctoral degree in physics, biophysics, radiological physics, health physics, or medical physics and have completed one year of documented, full time training in the appropriate field and also one year of documented, full time work experience under the supervision of a qualified expert in the appropriate field. To meet this requirement, the individual shall have performed the tasks required of a qualified expert during the year of work experience; or

3. Receive approval from DHHS/RHS for specific activities if he or she has:

a. A bachelor's degree in physics, biophysics, radiological physics, health physics, or medical physics; and

b. Completed 6 years of documented full time training and work experience in the appropriate field;

(2) A complete list of all individuals who will be providing services in New Hampshire under this registration;

(3) A description of the measuring instruments to be used for the type of service to be provided and the frequency of calibration of those instruments; and

(4) An attestation, signed and dated by the applicant, or management representative stating: "I certify that the applicant (1) understands and shall follow the relevant requirements of the New Hampshire Rules for the Control of Radiation (He-P 4000) applicable to the types of servicing or services to be provided under this registration and (2) shall adhere and require adherence to them and good radiation safety practices."

(e) No registered service provider shall perform services that are not specifically stated on the certificate of registration issued by DHHS/RHS.

(f) DHHS/RHS shall issue a certificate of registration provided that the requirements of He-P 4040.07 and the fee required by He-P 4070.06 have been met.

(g) The registered service provider shall retain the certificate of registration until it expires.

(h) Registration is renewable as described in He-P 4040.09.

**Readopt with amendment He-P 4040.07 through He-P 4040.11, effective 6-22-11 (Document # 9945-A), and renumber as He-P 4040.08 through He-P 4040.12, to read as follows:**

He-P 4040.08 Expiration of Certificates of Registration.

(a) Each certificate of registration for possession of a radiation or MRI machine shall expire at the end of the day on the first July 31 after issuance of the certificate.

(b) Each certificate of registration for servicing and services shall expire at the end of the day on the first July 31 after issuance of the certificate.

(c) The registration for any individual machine shall terminate upon disposal, permanent removal or change of ownership, of the machine as described in He-P 4040.05.

He-P 4040.09 Renewal of Certificates of Registration.

(a) Renewal of a certificate of registration for possession of a radiation or MRI machine shall be made in writing prior to August 1<sup>st</sup> of each year.

(b) The machine renewal application shall include the following:

(1) Updated or changed information about the radiation or MRI machine status since issuance of the most recent certificate of registration, including any of the following:

- a. Type of machine;
- b. Location of machine;
- c. Transfer of ownership
- d. Transfer to alternate site;
- e. Change in status from in use to storage;
- f. Change in status from storage to in use; or
- g. Addition of any radiation or MRI machine;

(2) A completed FORM DHHS/RHS A “Application for Radiation or Magnetic Resonance Imaging Machine Registration” (May, 2015) as required in He-P 4040.04 if any changes have been made;

(3) A completed FORM DHHS/RHS D “Certificate-Disposition or Change of Ownership of Radiation or MRI Machine” (May, 2015) as required in He-P 4040.05, if applicable; and

(4) A check made payable to “Treasurer- State of New Hampshire” for the appropriate fee listed in He-P 4070.06.

(5) An attestation signed and dated by the registrant, or a certifying officer signing on behalf of the registrant, attesting to the following: “I, the registrant or certifying officer signing on behalf of the registrant, understand and shall follow the relevant requirements of the New Hampshire Rules for the Control of Radiation (He-P 4000) and confirm that all of the information herein is complete and accurate.”

(c) Each prospective or renewing registrant who fails to submit the registration fee within 30 days of the date that the application and fee are due, shall be assessed an administrative fine of \$100 with the fee as described in He-P 4070.08.

(d) Renewal of registration as service providers pursuant to He-P 4040.07 shall be made in writing prior to August 1<sup>st</sup> of each year.

(e) The service provider application for a renewal of registration shall include the following:



(1) A signed and dated renewal of a certificate of registration for servicing and services shall be made on FORM DHHS/RHS-RSP “Annual Renewal of Radiation or MRI Machine-Related Service Provider Registration” (May, 2015) provided by DHHS/RHS;

(2) An attestation signed and dated by the applicant, or management representative stating “I certify that the applicant (1) understands and shall follow the relevant requirements of the New Hampshire Rules for the Control of Radiation (He-P 4000) applicable to the types of services or servicing to be provided under this registration and (2) shall adhere and require adherence to them and good radiation safety practices.”

(3) A check made payable to “Treasurer- State of New Hampshire” for the appropriate fee listed in He-P 4070.06.

He-P 4040.10 Assembler and/or Transferor Obligation.

(a) Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation or MRI machines shall register as a service provider and notify DHHS/RHS within 15 days of:

(1) The name and address of persons who have received these machines;

(2) The manufacturer, model, and serial number of each radiation or MRI machine transferred; and

(3) The date of transfer of each machine, if applicable.

(b) No person shall make, sell, lease, transfer, lend, assemble, or install radiation or MRI machines or the supplies used in connection with such machines unless such supplies and equipment, when properly placed in operation, meet the requirements of this chapter.

He-P 4040.11 Reciprocal Recognition of Out-of-State Radiation and MRI Machines.

(a) A person proposing to bring any radiation or MRI machine into New Hampshire from another state, for any use, shall apply to DHHS/RHS in writing at least 3 business days prior to use of the machine in the state.

(b) Any radiation or MRI machine used for demonstration purposes shall follow He-P 4040.11.

(c) Application for recognition of a person proposing to bring an out-of-state machine into New Hampshire shall be made on FORM DHHS/RHS-RP “Registration for Reciprocal Recognition of Out-of-State Machines” (May, 2015) provided by DHHS/RHS.

(d) The applicant shall provide, with the application, a fee equal to half the annual fee set out in He-P 4070.06, for each radiation or MRI machine the applicant proposes to bring into the state with the first application for that type of radiation or MRI machine in the calendar year.

(e) The reciprocity fee required by (d) above shall cover a period of one year from the time of application, at which time a new fee submittal shall be required.

(f) In the event an applicant proposes subsequently to bring into the state in the same calendar year a machine with a higher annual fee, the applicant shall provide with the application a fee equal to half the difference between the fees of the 2 types of machines.

(g) DHHS/RHS shall not grant approval to any application for an out-of-state radiation or MRI machine requiring a fee, if the fee does not accompany the application.

(h) DHHS/RHS shall refund the fee accompanying any application requiring one if it does not grant approval for that application.

(i) The applicant shall apply in writing for a waiver to use an out-of-state radiation or MRI machine with less than 3-business days prior written notification.

(j) DHHS/RHS shall grant a waiver of the 3-business day application limit on determining that adherence to the limit would endanger an individual's or the public's health and safety.

(k) The person entering the state under reciprocity shall:

(1) Comply with the rules in this chapter as they relate to radiation or MRI machines, their operators, and operations of the machines;

(2) Supply additional information as requested by DHHS/RHS for the purposes of protecting public and worker health and safety and ensuring the safe use of machines within the state; and

(3) Not operate an out-of-state machine within the state under reciprocity in excess of 180 calendar days per year.

(l) Any radiation or MRI machine shall be subject to unannounced inspection by DHHS/RHS during the duration of the out-of-state recognition of reciprocal registration.

He-P 4040.12 Radiation or MRI Machines in Storage.

(a) A radiation or MRI machine shall be categorized as a machine in storage if it meets the following conditions:

(1) The machine is registered with DHHS/RHS in accordance with the requirements of He-P 4040.04;

(2) The machine is physically disconnected from any source of operating electric power in one or more of the following ways:

a. By the removal of its power cord or plug, if so equipped;

b. By the removal of its direct connection from the facility's electrical wiring system, if so connected;

c. By the removal of its internal main fuse or circuit breaker, if so equipped; or

d. By having its external circuit breaker or electrical circuit disconnect locked in an electrically non-conducting condition with a key-operated or combination lock; and

(3) The machine has at its operating control or console a tag or label bearing the words "In storage."

(b) The placement of a machine into the storage status shall be recorded on FORM DHHS/RHS D “Certificate-Disposition or Change of Ownership of Radiation or MRI Machine (May, 2015) which shall be submitted to DHHS/RHS. Upon approval by DHHS/RHS, the status of the registered machine shall be changed to “in storage” while it remains out of service.

(c) A registrant shall not put into service or restore to service a machine registered as in storage until a completed DHHS/RHS D “Certificate-Disposition or Change of Ownership of Radiation or MRI Machine” (May, 2015) has been submitted and the difference between the fee for the machines in storage and the fee that would otherwise apply for such machine, as set out in He-P 4070.06, has been paid.

(d) DHHS/RHS shall not require machines in storage under the provisions of this section to meet the requirements in Parts He-P 4041 through He-P 4047, for that machine type.

(e) A registered machine approved of as in storage shall qualify for the fee specified in He-P 4070.06 for a machine in storage.

**Readopt He-P 4040.12, effective 1-11-14 (Document # 10505), and renumber as He-P 4040.13, to read as follows:**

He-P 4040.13 Waivers.

(a) DHHS/RHS has found that He-P 4040 applies to a variety of conditions and uses, and that the strict application of these rules may result in hardship or misapplication. The purpose of these waiver procedures is to accommodate those situations where strict adherence would not be in the best interest of the public.

(b) Any person who is or would be directly and adversely affected by the strict application of a rule in He-P 4040 may request a waiver, provided that such waiver does not contravene a federal statute or regulation, state statutory requirement, or state or federal constitutional requirement.

(c) Any person who wishes to request a waiver shall submit a written request for a waiver.

(d) The request for a waiver shall include the following information:

(1) The identification of the facility or activity to which the request relates;

(2) The specific citation to the He-P 4040 rule from which a waiver is sought;

(3) A full explanation of why a waiver is being requested;

(4) A full explanation of any alternate procedure, method, or other activity that is sought to be substituted for the procedure, method, or other activity that is required by the rule from which a waiver is being sought;

(5) The limit of duration requested for the waiver; and

(6) A full explanation of why the person believes that having the waiver granted will not adversely impact the public health or safety, the environment, or property.

(e) All requests for a waiver shall be submitted to DHHS/RHS.

(f) Where a request for a waiver relates to an application for a registration, the person requesting the waiver shall submit the request as part of such application, or as soon thereafter as the person identifies the need for the request.

(g) DHHS/RHS shall grant a request for a waiver if the requesting party demonstrates that:

(1) The waiver shall not result in an adverse effect to public health or safety, the environment, or property; and

(2) Strict compliance with the applicable section of He-P 4040 rule:

a. Will result in an adverse effect to the public health or safety, the environment, or property; or

b. Is technologically infeasible.

(h) DHHS/RHS shall send written notification to the person requesting the waiver of the determination on the request. If the waiver is submitted as part of the registration application and is granted, it shall become part of the registration document.

#### APPENDIX

<u>Rule Number</u>	<u>RSA Implemented</u>
He-P 4040.01 - 4040.12	RSA 125-F:5, IV & V; RSA 125-F:7, II-IV, F: 13
He-P 4040.13	RSA 541-A:22, IV